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Examiner: P. Nolan

Group: 1644

Date: December 20, 2004

Client Code: 0148

Facsimile No.: 703-872-9306

From: Alice O. Carroll

Subject: Paper: Declaration of Don E. Griswold, Ph.D. under 37 C.F.R. §1.132

Docket No.: 0148.1135-010

Applicant: George Treacy

Serial No.: 09/942,075

Filing Date: August 28, 2001

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Number of pages including this cover sheet: 38

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AOC/HL
December 3, 2004

PATENT APPLICATION
Attorney's Docket No.: 0148.1135-010

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: George Treacy

Application No.: 09/942,075

Group Art Unit: 1644

Filed: August 28, 2001

Examiner: Nolan, P.

Confirmation No.: 6161

For: ANTI-TNF α ANTIBODIES IN THERAPY OF ASTHMA

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|---|------------------------|
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| Typed or printed name of person signing certificate | |

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DECLARATION OF DON E. GRISWOLD, PH.D.
UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Don E. Griswold, Ph.D., declare and state that:

1. I have been employed at Centocor, Inc., 200 Great Valley Parkway, Malvern, PA 19355 since 2001, most recently as Senior Director and Head, Department of Immunobiology. I have been advised that Centocor is the assignee of the entire right, title and interest of the subject application.

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2. I received my Ph.D. degree in Pharmacology from the University of Kansas Medical Center, Kansas City, Kansas in 1969. A copy of my curriculum vitae, which describes my educational and professional experience, is attached as Exhibit A.

3. I have published extensively in refereed publications, most of which have been focused in the areas of inflammation, immunopharmacology, and pulmonary and cutaneous pharmacology. A list of publications authored or co-authored by me is included as part of my curriculum vitae.

4. I have read the Office Action dated May 18, 2004, the Office Action dated August 21, 2003, and the art cited by the Examiner in the Office Actions, in particular the cited references of Konno *et al.* (*Int. Arch. Allergy Immunol.*, 105:308-316 (1994)), Shah *et al.* (*Clin. Exper. Allergy*, 25:1038-1044 (1995)), and Lukacs *et al.* (*J. Immunol.*, 154:5411-5417 (1995)). I have also read the patent application and the presently pending claims that were rejected in the Office Action.

5. Konno *et al.* examined the influence of roxithromycin (RXM), a macrolide antibiotic, and polyclonal rabbit anti-mouse TNF α antibodies on cytokine appearance in mouse lung extract induced by lipopolysaccharide (LPS) inhalation and on bronchial responsiveness (BR) to methacholine (Mch) in LPS-treated mice. Although inhalation of LPS causes pulmonary inflammatory responses and an increase in BR, it is not considered as an animal model for asthma. Thus, results obtained using the LPS mouse model would not provide evidence for the treatment of asthma.

6. Shah *et al.* summarize the scientific rationale available in 1995 that supported TNF α as an attractive target for asthma. In particular, Shah *et al.* report results showing (1) increased levels of TNF α in sputum of patients with acute attacks of asthma; (2) increased number of cells expressing TNF α mRNA in bronchoalveolar lavage (BAL) fluid of stable atopic asthmatic subjects when compared to BAL of normal subjects; and (3) TNF α levels up

CURRICULUM VITAE**Don E. Griswold, Ph.D.****November, 2004**

ADDRESS: Centocor, Inc.
Department of Immunobiology
200 Great Valley Parkway
Malvern, PA USA 19355-1307

TELEPHONE: (610) 651-6994
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DATE AND PLACE OF BIRTH: June 24, 1943, Newton, Kansas

EDUCATION:

| <u>Institution</u> | <u>Degree</u> | <u>Date Received</u> | <u>Major(s)</u> |
|---|---------------|----------------------|-------------------------------|
| University of Kansas Medical Center Kansas City, Kansas | Ph.D. | 1969 | Pharmacology |
| Emporia State University Emporia, Kansas | B.A. | 1965 | Microbiology and Chemistry |

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November, 2004

EXHIBIT

A